



MAIL STOP - PCT  
Docket No.: 27577U

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: DUNKERN, et al.

Art Unit: XX

Appl. No.: 10/590,992

Examiner: XX

Appl. Filing Date: August 29, 2006

Intl. Appl. No.: PCT/EP2005/050958

Intl. Appl. Filing Date: March 3, 2005

For: **NOVEL USE FOR PDE5 INHIBITORS**

TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:


Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

1. Information Disclosure Statement; and
2. PTO Form-1449 with 26 references cited, and copies of all 26 references cited.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

November 14, 2006

  
Gary M. Nath, Reg. No. 26,965  
Sheldon M. McGee, Reg. No. 50,454  
Customer No. 34375

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars: [NOTE: One only of items a, b, c, and d must be checked.]

a. ☒ [XXX] The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

b. ☐ [ ] The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed statement is accompanied by [check one]:

☐ [ ] i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e), or

☐ [ ] ii. a check in the amount required by 37 C.F.R. 1.17(p).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./

- c. ☐ The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.
- ☐ Certification report(e) below; and
- ☐ a check in the amount as required by 1.17(p).
- d. ☐ The enclosed statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.
- e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]
- ☐ I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,
- or
- ☐ I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- or
- ☐ Appropriate certification is attached.
- f. [XXX] If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

g. [XXX] Copies of the documents are attached herewith with a completed PTO Form-1449.

or

[ ] Copies of the documents are not attached, with a completed PTO Form-1449 as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

and / or

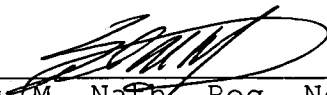
[ ] Copies of US Patents/Publications not attached, with a completed PTO Form-1449 as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

November 14, 2006

  
Gary M. Nath, Reg. No. 26,965  
Sheldon M. McGee, Reg. No. 50,454  
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PTO FORM-2449

**INFORMATION DISCLOSURE  
CITATION**

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Examiner: XX

**U.S. PATENT DOCUMENTS**

Exam. Initial	Document No.	Issue/Public. Date	Inventor	Filed Date
A1				

**FOREIGN PATENT DOCUMENTS**

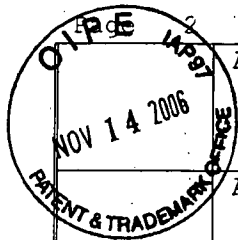
Exam. Initial	Document No.	Public. Date	Country	Translation
A2	0 758 653 A1	2/19/1997	EP	N/A
A3	1 317 924 A1	6/11/2003	EP	N/A
A4	0 985 671 A1	3/15/2000	EP	N/A
A5	03/51346 A2	6/26/2003	WO	N/A
A6	01/27112 A1	4/19/2001	WO	N/A
A7	02/089808 A1	11/14/2002	WO	N/A
A8	98/38168 A1	9/3/1998	WO	N/A

**OTHER**

(Including Author, Title, Date, Pertinent Pages, etc.)

Exam. Initial	
A9	Ghofrani, H.A., et al., "Sildenafil for treatment of lung fibrosis and pulmonary hypertension: a randomised controlled trial", <u>THE LANCET</u> , Vol. 360, pg. 895-900, (2002).
A10	Ghofrani, H.A., et al., "Oral Sildenafil as Long-Term Adjunct Therapy to Inhaled Iloprost in Severe Pulmonary Arterial Hypertension", <u>Journal of the American College of Cardiology</u> , Vol. 42, No. 1, pg. 158-164, (2003).
A11	Ghofrani, H.A., et al., "Sildenafil for Long-Term Treatment of Nonoperable Chronic Thromboembolic Pulmonary Hypertension", <u>Am J Respir Crit Care Med</u> , Vol. 167, pg. 1139-1141, (2003).
A12	Cunningham, D.R., et al., "The Effects of Chronic Hypoxemia on Central Auditory Processing in Patients with Chronic Obstructive Pulmonary Disease", <u>Ear and Hearing</u> , Vol. 6, No. 6, pg. 297-303, (1985).
A13	Bianco, A., et al., "Effect of Sildenafil on Diabetic Gastropathy", <u>Diabetes Care</u> , Vol. 25, No. 10, pg. 1888-1889, (2002).
A14	Barnes, P.J., "Cyclic nucleotides and phosphodiesterases and airway function", <u>Eur Respir J</u> , Vol. 8, pg. 457-462, (1995).
A15	Halcox, J.P.J., et al., "The Effect of Sildenafil on Human Vascular Function, Platelet Activation, and Myocardial Ischemia", <u>Journal of American College of Cardiology</u> , Vol. 40, No. 7, pg. 1232-1240, (2002).
A16	Presberg, K.W., et al., "Pathophysiology of pulmonary hypertension due to lung disease", <u>Current Opinion in Pulmonary Medicine</u> , Vol. 9, pg. 131-138, (2003).
A17	Prasad, S., et al., "Sildenafil in Primary Pulmonary Hypertension", <u>The New England Journal of Medicine</u> , Vol. 343:1342, No. 18, pg. 1-3, (2000).
A18	Nehra, A., et al., "Sildenafil citrate, a selective phosphodiesterase type 5 inhibitor: urologic and cardiovascular implications", <u>World J Urol</u> , Vol. 19, pg. 40-45, (2001).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./



of 2

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A19	Michelakis, E.D., et al., "Long-Term Treatment With Oral Sildenafil Is Safe and Improves Functional Capacity and Hemodynamics in Patients With Pulmonary Arterial Hypertension", <u>Circulation</u> , Vol. 108, pg. 2066-2069, (2003).
A20	Kruuse, C., et al., "Migraine can be induced by sildenafil without changes in middle cerebral artery diameter", <u>Brain</u> , Vol. 126, pg. 241-247, (2003).
A21	Prickaerts, J., et al., "Effects of Two Selective Phosphodiesterase Type 5 Inhibitors, Sildenafil and Vardenafil, on Object Recognition Memory and Hippocampal Cyclic GMP Levels in the Rat", <u>Neuroscience</u> , Vol. 113, No. 2, pg. 351-361, (2002).
A22	Incalzi, R.A., et al., "Cognitive impairment in chronic obstructive pulmonary disease: A neuropsychological and spect study", <u>J Neurol</u> , Vol. 250, pg. 325-332, (2003).
A23	Watkins, C.C., et al., "Insulin restores neuronal nitric oxide synthase expression and function that is lost in diabetic gastropathy", <u>The Journal of Clinical Investigation</u> , Vol. 106, No. 3, pg. 373-384, (2000).
A24	Zhang, R., et al., "Sildenafil (Viagra) Induces Neurogenesis and Promotes Functional Recovery After Stroke in Rats", <u>Stroke</u> , Vol. 33, pg. 2675-2680, (2002).
A25	Zhang, R., et al., "Nitric Oxide Enhances Angiogenesis via the Synthesis of Vascular Endothelial Growth Factor and cGMP After Stroke in the Rat", <u>Circ Res.</u> , Vol. 92, pg. 308-313, (2003).
A26	Yamamoto, T., et al., "Chronic administration of phosphodiesterase type 5 inhibitor suppresses renal production of endothelin-1 in dogs with congestive heart failure", <u>Clinical Science</u> , Vol. 103 (Suppl. 48), pg. 2585-2625, (2002).
A27	Reffelmann, T., et al., "Therapeutic Potential of Phosphodiesterase 5 Inhibition for Cardiovascular Disease", <u>Circulation</u> , Vol. 108, pg. 239-244, (2003).
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Examiner

/Marcos Sznaidman/

Date Considered

04/30/2008

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP'609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./